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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,586	12/21/2004	Kazushige Moriyama	263494US0PCT	7701
22850	7590	08/02/2006	EXAMINER	
C. IRVIN MCCLELLAND OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			DIRAMIO, JACQUELINE A	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/518,586	MORIYAMA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jacqueline DiRamio	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 May 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Status of the Claims***

The cancellation of claims 1 – 15, as well as the addition of new claims 16 – 25, is acknowledged.

Currently, claims 16 – 25 are pending and under examination.

***Withdrawn Objections and Rejections***

All previous objections to the claims are withdrawn in view of Applicant's cancellation of all previous claims.

All previous rejections of the claims are withdrawn in view of Applicant's cancellation of all previous claims.

***Response to Arguments***

Applicant's arguments, see p6-7, filed April 26, 2006, with respect to the rejection(s) of the claim(s) under 35 U.S.C 102(b) have been fully considered and are persuasive. New claim 16, which requires a chemiluminescent substrate comprising at least one dioxetane, an enzyme, and a water soluble macromolecular quaternary ammonium, sulfonium, or phosphonium salt, which has been treated with an oxidizing agent or a reducing agent, is not fully taught or anticipated by the previously applied references of Akhavan-Tafti et al. (US 6,045,727), Voyta et al. (GB 2 233 451 A), Bronstein et al. (US 5,753,436 or US 5,112,960), or Okada et al. (US 5,094,939).

Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

## **NEW GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16 – 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bronstein et al. (US 5,753,436) in view of Akhavan-Tafti et al. (US 6,045,727).

Bronstein et al. teach a chemiluminescence method in a solid phase immunoassay, comprising contacting at least one antigen and/or antibody immobilized on fine solid carriers dispersible in a liquid medium with a chemiluminescent substrate comprising at least one dioxetane, an enzyme for performing chemiluminescence, and

at least one chemiluminescent enhancer, wherein the chemiluminescence enhancer typically comprises a water soluble polymeric quaternary ammonium, phosphonium or sulfonium salt, which is capable of enhancing the emission light caused by the reaction of the chemiluminescent substrate with the enzyme (see column 7, lines 23-67; column 8, lines 1-67; column 9, lines 1-10; column 10, lines 1-13 and column 15).

However, Bronstein et al. fail to teach the additional treatment with an oxidizing or reducing agent, such as those listed in Applicant's claim 24.

Akhavan-Tafti et al. teach a chemiluminescence method of reacting phosphotase-labeled specific binding partners in the presence of a chemiluminescence compound with an added chemiluminescence enhancer, wherein the method can comprise a solid phase immunoassay using an antigen and/or antibody immobilized onto fine solid carriers dispersible in a liquid medium. The chemiluminescence enhancer typically comprises a surfactant compound, such as a quaternary ammonium or phosphonium salt. The method further includes the addition of an effective amount of a background reducing agent (oxidizing or reducing) to the chemiluminescent composition, wherein an effective background reducing agent is a sulfite salt, such as sodium sulfite. The inclusion of the background reducing agent is beneficial in order to prevent the accumulation of background chemiluminescence over a period of time, as well as to improve the ratio of specific signal produced by reaction of the composition with a phosphatase enzyme to background chemiluminescence (see column 14, lines 49-67; column 15, lines 1-36; column 21, lines 45-63; column 22, lines 37-67; column 23, lines 1-27; column 24, lines 39-67; and column 25, lines 1-53).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the method of Bronstein et al. the treatment with a background reducing agent, i.e. oxidizing or reducing agent, as taught by Akhavan-Tafti et al. because Akhavan-Tafti et al. teach the benefit of including a background reducing agent in order to prevent the accumulation of background chemiluminescence over a period of time, as well as to improve the ratio of specific signal produced by reaction of the composition with a phosphatase enzyme to background chemiluminescence.

With respect to Applicant's claim 17, Bronstein et al. teach that the chemiluminescence enhancer, which comprises a water soluble macromolecular quaternary salt, has a molecular weight from about 20,000 to about 70,000 daltons (see column 11, lines 4-8).

With respect to Applicant's claim 18, Bronstein et al. teach that the dioxetane has the formula as presented by Applicant, along with the recited limitations (see column 7, lines 54-67; and column 8, lines 1-17).

With respect to Applicant's claims 9-21, Bronstein et al. teach that the chemiluminescent enhancer is prepared from a quaternary salt based on phosphonium, sulfonium, or ammonium moieties, wherein the quaternary salt is polymerized and preferably comprises a poly(vinyl benzyl quaternary ammonium salt) (see columns 10-13; and claim 3).

With respect to Applicant's claims 22 and 23, Bronstein et al. and Akhavan-Tafti et al. both teach that the solid carrier can comprise a bead or particle, wherein Akhavan-Tafti et al. teach that the particles specifically comprise magnetic particles (see column 15 of Bronstein et al.; and column 25, lines 1-53, particularly lines 5 and 52 of Akhavan-Tafti et al.).

With respect to Applicant's claim 24, Akhavan-Tafti et al. teach that the background reducing agent, i.e. oxidizing or reducing agent, comprises sodium sulfite (see column 21, lines 45-63).

With respect to Applicant's claim 25, Bronstein et al. teach that the enzyme comprises alkaline phosphatase (see column 9, lines 1-10).

### ***Conclusion***

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Akhavan-Tafti et al. (US 2002/0019553);

L.J. Bollyky (US 3,704,231); and

EI Alaoui et al. (US 6,124,109).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

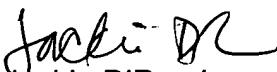
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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